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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,851	08/07/2006	Chia Ying Lin	2115D002504/NPB	6572
27572	7590	12/11/2007		
HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER BAHTA, KIDEST	
			ART UNIT	PAPER NUMBER
			2125	
			MAIL DATE	DELIVERY MODE
			12/11/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

12

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/553,851	LIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kidest Bahta	2125	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,18 and 20 is/are rejected.
- 7) ☒ Claim(s) 8-17 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____                                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/20/05</u> .  | 6) <input type="checkbox"/> Other: ____                           |

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Haussecker et al. (US 2004/0213443).

Regarding claim 1, Haussecker a method of designing an inter body fusion cage comprising: defining operational parameters for the cage (abstract); defining a macroscopic structural layout for the cage satisfying the operational parameters (Abstract); dividing the macroscopic structural layout of the cage into a plurality of discreet sub-segments ([Fig. 1, Fig. 3, element 330]); defining a density distribution of the macroscopic structural layout by determining a density level for each sub-segment ([0019]); and defining a microscopic structural layout for the cage by assigning pre-selected microstructures to the sub-segments in accordance with the density level of each sub-segment ([0019], [0109], [0119]).

**Regarding claims 3-7, Haussecker discloses,**

3. The method of claim 1 wherein the step of defining the macroscopic structural layout further comprises executing a topology optimization algorithm for the cage based on the operational parameters ([0112]).

4. The method of claim 1 wherein the step of defining the microscopic structural layout further comprises executing a topology optimization algorithm for the cage based on the density distribution ([0109]).

5. The method of claim 1 further comprising integrating the microscopic structural layout and the macroscopic structural layout to provide a designed cage ([0014]-0015], [0019]).

6. The method of claim 1 further comprising manufacturing the designed cage with solid free-form fabrication techniques (.).

7. The method of claim 1 further comprises categorizing the sub-segments into different ranks based on the density level of each sub-segment, each rank being defined by a different length scale; and homogenizing the microstructure of a particular rank to an upper rank ([0112]).

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haussecker et al. (US 2004/0213443) in view of Malone (US 2002/0169507).

Regarding claim 2, Haussecker discloses the limitations of claim 1 as stated in Par. 1, but fails to disclose the limitations of claim 2. Malone discloses the limitations of claim 2; the operational parameters further comprise stability, porosity, and compliance ([0028]).

Regarding claims 18 and 20, Haussecker discloses that a method of designing an inter- body fusion cage comprising: generating a global density distribution under physiologic loading for the cage using a global topology optimization algorithm including (Fig. 4-6).

Haussecker fails to disclose Malone discloses a stability constraint that limits total displacement of the cage at a desired surface to be less than a target value; and a total porosity constraint that ensures desired biofactor delivering ability and compliance; segmenting the global density distribution architecture into a plurality of regions, each region having a material phase selected from: a low porosity solid phase; a high porosity solid phase; and a voided phase; and defining a porous microstructure for the cage by generating periodic microstructures for the regions having the high porosity solid phase and low porosity solid phase using a microstructure topology optimization method ([0041], Fig. 9-11).

Malone discloses a stability constraint that limits total displacement of the cage at a desired surface to be less than a target value ([0028])([0012]); and a total porosity constraint that ensures desired biofactor delivering ability and compliance ([0031]); segmenting the global density distribution architecture into a plurality of regions, each region having a material phase selected from: a low porosity solid phase; a high porosity solid phase; and a voided phase (Fig. 6-8); and defining a porous microstructure for the cage by generating periodic microstructures for the regions having the high porosity solid phase and low porosity solid phase using a microstructure topology optimization method ([0041], Fig. 9-11).

It would have been obvious to a person of ordinary skill in the art at the time of invention was made to modify the teachings of Haussecker with the teachings of Malone provided an end closure means for effecting the closure of the posterior end of a fusion cage while establishing a desired occlusion pattern of apertures in the wall of the fusion cage. The closure means comprises a non-perforated sealing member to effect the closure of the posterior end of the internal cavity of the fusion cage and one or more occluding surfaces extending from the sealing member essentially parallel to the longitudinal axis of the fusion cage so as to establish one or more desired zones or patterns of occluded apertures amongst the plurality of apertures in the cage body.

### ***Allowable Subject Matter***

3. Claims 10-17 and 19-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kidest Bahta whose telephone number is 571-272-3737.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Picard can be reached on 571-272-3749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kidest Bahta



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